MOTION FILED

FEB 13 2004

No. 03-862

In the Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA KRIEFALL, ET AL.,

Respondent.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF OF THE AMERICAN MEAT INSTITUTE, THE NATIONAL CHICKEN COUNCIL, THE NATIONAL FOOD PROCESSORS ASSOCIATION, THE NATIONAL MEAT ASSOCIATION, THE NATIONAL TURKEY FEDERATION, THE NORTH AMERICAN MEAT PROCESSORS ASSOCIATION, AND THE SOUTHWEST MEAT ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Under Rule 37.2 of the Rules of this Court, the American Meat Institute, the National Chicken Council, the National Food Processors Association, the National Meat Association, the National Turkey Federation, the North American Meat Processors Association, and the Southwest Meat Association move for leave to file the accompanying brief in support of the petition for a writ of certiorari. Counsel for petitioner has consented to the filing of this brief, but counsel for certain of respondents have declined to grant consent.

The issue presented by the petition – whether the Food Safety and Inspection Service, acting on delegated authority from the U.S. Secretary of Agriculture, is "powerless" (Pet. App. 19a) to decide that there is a distinction between intact and non-intact meat in deciding what meat is "adulterated" under the Federal Meat Inspection Act (FMIA) – is of profound importance to the meat and poultry industry and to consumers nationwide. Members of *amici curiae* include hundreds of meat processors and packers that are subject to pervasive federal regulation, including mandatory continuous inspection, by the U.S. Department of Agriculture (USDA) or state programs that USDA deems at least equivalent. Under the Wisconsin Court of Appeals' novel interpretation, members of *amici curiae* are subject to civil and criminal liability for supplying meat that complies fully with federal requirements. *Amici curiae* are well situated to assist the Court in understanding the enormous practical importance of the FMIA issue presented.

Amicus curiae American Meat Institute (AMI) is a national trade association representing packers, processors, suppliers, and distributors of meat and meat food products. AMI has been a force in the meat processing community since 1906 – the year the first federal meat inspection statute was passed.

Amicus curiae National Chicken Council (NCC) is a national, nonprofit trade association representing the chicken industry, including producers, processors, and distributors of chicken and chicken products. NCC members account for more than 95 percent of the chicken produced in the United States.

Amicus curiae National Food Processors Association (NFPA) is the principal scientific and technical trade association

for the food industry. NFPA members process and package fruits, vegetables, meat, fish, and speciality food products.

Amicus curiae National Meat Association (NMA) is a national trade association that has been advocating the interests of the meat industry since 1946. NMA members include packers, processors, and distributors of meat and meat products.

Amicus curiae National Turkey Federation (NTF) is the only national trade association representing the turkey industry exclusively. NTF represents more than 95 percent of the turkey industry in the United States, including breeders, hatchery owners, growers, and processors.

Amicus curiae the North American Meat Processors Association (NAMP) – founded in 1942 – is an international, not-for-profit trade association representing the needs of meat, poultry, seafood, and game processors.

Amicus curiae Southwest Meat Association (SMA) is a trade association representing packers and processors of meat and meat food products. SMA's members are located in Texas, Louisiana, Oklahoma, Arkansas, and New Mexico.

Amici – who collectively represent more than 95 percent of all companies engaged in processing beef, chicken, turkey, pork, lamb, and veal products in the United States – have a strong interest in persuading this Court to grant review, given the detrimental effect the Wisconsin Court of Appeals' decision, if allowed to stand, would have on the meat processing industry. The court below disregarded some of the FMIA's principal purposes as well as the enormous harm to the industry that would result from the court of appeals' decision to strip the Secretary of Agriculture of her power to interpret the FMIA's key term – "adulterated." In reaching its decision, the court completely disregarded the contradictory interpretation reached by the Secretary as well as scientific research supporting the Secretary's view. The court's approach was wrong and in conflict with this Court's teachings. See *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842-843 (1984) (holding that a court should take an administrative interpretation of an ambiguous statutory term into account); *Alaska Dep't of Envtl. Conservation* v. *EPA*, 2004 WL 86284, *16 (U.S. Jan. 21, 2004) ("We normally accord particular deference to an agency interpretation

of long-standing duration, recognizing that well-reasoned views of an expert administrator rest on a body of experience and informed judgment to which courts and litigants may properly resort for guidance.") (internal citations and quotations omitted).

Members of *amici* are subject to the FMIA and its implementing regulations when engaged in their core business of meat processing and packing. And, if this Court denies review, they will be faced with possible civil and criminal penalties for distributing products that comply with USDA standards and pass federal inspection. Such a sweeping invalidation of the Secretary's longstanding, sophisticated, and nuanced interpretation of "adulterated" is of great concern to *amici*, who respectfully submit that its implications are far reaching enough, and its incorrectness clear enough, to cry out for this Court's review. *Amici* should therefore be granted leave to file the attached brief.

Respectfully submitted.

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FEBRUARY 2004

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BRIEF OF *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The interest of the *amici curiae* is described in the accompanying motion for leave to file this brief.

STATEMENT

The decision reached by the Wisconsin Court of Appeals – that any raw meat containing natural pathogens such as *E. coli* O157:H7 bacteria is adulterated and therefore unfit for human consumption – directly contradicts applicable U.S. Department of Agriculture (USDA) standards. The lower court's complete disregard for the expert agency's views calls into question the continuing power of the federal government to set the standards for meat sold in interstate commerce, opens the door for States to adopt widely varying and inconsistent interpretations of the Federal Meat Inspection Act, and undermines the extensive – and nationally uniform – system of federal meat inspection and oversight that has been in place for decades pursuant to Congress's desire to "prevent and eliminate burdens upon [interstate or foreign] commerce" while *also* protecting consumer health. 21 U.S.C. § 602.

A. Federal Regulation Of The Meat Industry

For nearly a century, federal authorities have been responsible for helping to ensure the safety of the Nation's food supply through (among other things) prevention of the sale of "adulterated" food products.[2] The meat industry – including

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amici* state that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the *amici*, their members, or their counsel, has made a monetary contribution to this brief.

[2] In 1906, in response to publication of Upton Sinclair's famous book *The Jungle* (a graphic exposé of unsanitary conditions prevalent in the meat industry), Congress passed two statutes – the Pure Food and Drugs Act and the Federal Meat Inspection Act – that prohibited the sale of

entities involved in all aspects of meat preparation, from slaughter of livestock to sale of meat in retail establishments – is subject to the Federal Meat Inspection Act (FMIA or Act), 21 U.S.C. §§ 601-695, which establishes a comprehensive, uniform, national system for oversight of the preparation and sale of meat food products.

In enacting the FMIA, Congress recognized the importance of meat to the Nation's food supply and the dangers associated with insufficient oversight:

> Unwholesome, adulterated, or misbranded meat and meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. * * * [R]egulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 U.S.C. § 602. Since the Act's passage in 1906, Congress has amended it repeatedly – most significantly in 1967 – to ensure that the federal system is up to date and to withdraw all but the most limited power from the States. See 60 Fed. Reg. 6774, 6776 (Feb. 3, 1995) (describing the history of the FMIA).

The FMIA strives to accomplish all these objectives simultaneously by, among other things, prohibiting the sale of "adulterated" meat. 21 U.S.C. § 602. It defines "adulterated," in pertinent part, as follows:

"adulterated" food. See James Harvey Young, *The Long Struggle for the 1906 Law*, FDA CONSUMER, June 1981, *available at* http://vm.cfscan.fda.gov/~lrd/history2.html.

> The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance * * * which may, in the judgment of the Secretary, make such article unfit for human food;
>
> * * *
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to the health.

21 U.S.C. § 601(m); see also 9 C.F.R. § 301.2 (adopting paragraphs (1), (3), and (4) of the definition of "adulterated").

To prevent adulterated meat from entering the food supply, Congress created a detailed, extremely intrusive federal oversight and inspection system and placed the responsibility for it in the hands of the Secretary of Agriculture, who in turn has delegated authority to the Food Safety and Inspection Service (FSIS). See 21 U.S.C. §§ 603, 604, 606, 608, 621, 678; 7 C.F.R. § 2.53(a)(2)(ii). In addition, Congress charged the Secretary with broad responsibility for establishing rules and regulations under the Act. See, *e.g.*, *id.* §§ 602, 608, 621.

Pursuant to that authority, the Secretary – among other things – prescribes rules regarding manufacturing processes and pace, sets plant sanitation standards, and employs agents at *each and every* federally inspected establishment to inspect meat at various stages of the preparation process. 60 Fed. Reg. at 6775; see generally 21 U.S.C. §§ 603-610, 612-613, 615; 9 C.F.R. §§ 307.1-.5, 310.1, 416.2-.6; 61 Fed. Reg. 38,806, 38,855 (July 25, 1996). Federal inspectors ensure compliance with the agency's sanitation standards, and refuse to allow the sale of meat products from facilities that fail inspection. 21 U.S.C. § 608.

Petitioner and members of *amici* are not merely subject to federal standards; they must have federal inspectors in their plants to examine livestock before slaughter, carcasses after slaughter, and meat products before distribution. See Pet. 5 (citing 60 Fed. Reg. at 6775-6777). The inspectors' organoleptic inspections (using sight, touch, and smell), which have been employed by federal inspectors for decades, are supplemented by sampling and statistical process methods identified in each facility's individualized plan.[3] Report to Cong. on the Consumer Safety Officer Initiative (FSIS Feb. 15, 2000), *available at* http://fsis.usda.gov/oa/congress/cso_report.htm. All "products found not to be adulterated" by the inspectors are marked "[i]nspected and passed," while all "products found

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[3] These plans – called Hazard Analysis and Critical Control Point (HACCP) plans – are hazard analysis systems that promote food safety by methodically identifying specific hazards in advance of processing so that they may be controlled. DENNIS R. JOHNSON & THE FOOD INSTITUTE, HACCP & U.S. FOOD SAFETY GUIDE § 5.3 (1996). In the late 1990s, the Secretary required each federally inspected plant to conduct a "hazard analysis" to "determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to reduce those hazards." 9 C.F.R. § 417.2(a). Each plant was then required to submit a written plan. *Id.* §§ 417.2-.3, 417.8 Plans accepted by USDA function like regulations in that all products from a noncompliant facility can be deemed "adulterated." *Id.* § 417.2(e).

adulterated" are marked "[i]nspected and condemned." 21 U.S.C. § 606. Those who violate the Act or USDA's regulations are subject to civil and criminal liability as well as a vast array of administrative sanctions, including the seizure and condemnation of meat and the withdrawal of federal inspection at an offending facility (thus shutting it down). *Id.* §§ 671-676.

In sharp contrast to the Secretary's broad power, the States' power is extremely limited: the Secretary and the States share power over products that are "adulterated or misbranded" under the federal scheme and that have left processing plants; and the States are permitted to have their own inspection programs if they are "at least equal to" federal standards. *Id.* §§ 661(c), 678,. Importantly, any state requirement that is "in addition to, or different" from, those issued by the Secretary is expressly preempted. *Id.* § 678.

B. Foodborne Diseases and *E. Coli* O157:H7

The United States' food supply is extremely safe, but foodborne diseases will always present challenges to our national food safety system. Institute of Food Technologists, *IFT Expert Report on Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century* (IFT Report), March 2002, *available at* http://www.ift.org/pdfs/microfs/webreport.pdf.[4] Microbiological disease-causing organisms such as *E. coli* are among the hardest sources of foodborne illness to detect and control.

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[4] In its report (at 4), the Institute of Food Technologists explains:

> Foodborne illness is not a simple problem in need of a solution; it is a complex combination of factors that must be managed on a continual basis. Aside from the inherent ability of pathogens themselves to evolve, pathogens' victims and the microbial environment play a role in the changing nature of foodborne illnesses, opening new niches and creating new vulnerabilities. No matter how sophisticated and complex a system is developed, food safety management is never finished or complete, because change is constant.

Like many pathogens, *E. coli* is a species of bacteria that naturally exists in warm-blooded animals, usually without causing illness to the host. Pet. 8; IFT Report at 27. The type of *E. coli* at issue in this case – O157:H7 (hereinafter *E. coli* O157) – is an elusive and virulent strain first reported as a foodborne pathogen in 1982. *Ibid.* And, although it is estimated that as many as half of all cattle carry *E. coli* O157 at some time in their lives, there is nevertheless a "low incidence of disease" associated with this bacterium. *Id.* at 28.

Despite that low incidence of disease, USDA and other public health organizations have long recommended that consumers take steps to protect themselves from illness caused by *E. coli* O157. To that end, federal authorities have repeatedly explained that proper cooking kills harmful bacteria in meat products (see Pet. 8), and have consistently advised consumers of the need to wash any dish, utensil, or surface that comes into contact with raw meat to prevent cross-contamination. See 9 C.F.R. § 317.2(1) (requiring proper handling and safe cooking instructions on labels of packaged raw meat); http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm.

In 1994, USDA decided to take an additional protective measure: it declared *ground* beef containing *E. coli* O157 to be "adulterated" within the meaning of the FMIA, and began testing ground beef samples for the presence of this bacterium. See 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002). USDA announced that ground meats containing *E. coli* O157 are adulterated, whereas intact cuts of meat bearing *E. coli* O157 are not. 64 Fed. Reg. 2804 (Jan. 19, 1999).[5]

Since that pronouncement, USDA has continued to gather information about *E. coli* O157 and its prevalence in meat. Recent scientific research and improvements in testing

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[5] The Secretary recently reaffirmed the safety of properly cooked intact cuts of meat, describing the risk of illness associated with *E. coli* O157 as "minuscule, regardless of the initial contamination level or susceptibility of the consumer." 67 Fed. Reg. 62,334 (Oct. 7, 2002).

techniques have led the agency to conclude that the bacterium is more common than previously thought. 67 Fed. Reg. 62,326. Consequently, in 2002, the FSIS instructed federally inspected processing plants to reassess their HACCP plans to ensure that they include measures designed to "prevent, eliminate, or reduce the presence of *E. coli* O157:H7 in their products." *Id.* at 62,332. Significantly, however, the Secretary left unchanged the rule that intact meat bearing *E. coli* O157 is not adulterated.[6]

C. The Proceedings Below

This case arises from injuries suffered by patrons of an E&B Sizzler restaurant who allegedly ate food from the salad bar that had become cross-contaminated with *E. coli* O157. Pet. 11. Respondents filed a common law tort action against numerous parties, including petitioner Excel Corporation.

Excel supplied intact cuts of raw meat to the Sizzler franchise at issue. Pet. App. 10a-11a. Before leaving Excel's facility, the meat had passed USDA inspection and was labeled with safe handling instructions. See *id.* at 17a.

Excel was granted summary judgment in the trial court. Pet. App. 52a. The court relied on the Secretary's determination that intact meat containing surface *E. coli* O157 is not adulterated within the meaning of the FMIA. Pet. App. 48a-49a. The trial court ruled that the Act and its comprehensive regulatory scheme preempt contrary state laws, including "civil suits against meat processors like Excel." *Id.* at 50a.

The Wisconsin Court of Appeals reversed, holding that intact cuts of meat containing *E. coli* O157 are adulterated. Pet. App. 19a-27a. The court of appeals arrived at that conclusion after determining that no deference would be given to the Secre-

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[6] Contrary to the lower court's suggestion (Pet. App. 35a), the Secretary has never ruled that *E. coli* O157 must be eliminated altogether from meat processing facilities and meat products. She has ruled, however, that inspectors must have "zero tolerance" for visible contaminants. See Pet. 10 n.2.

tary's rules regarding *E. coli* O157 because Congress delegated no power to interpret the statutory term "adulterated" to the Secretary (except in one limited area not applicable to this case). *Id.* at 13a, 16a, 19a. Without taking either the Secretary's views or longstanding industry practice into account, the appellate court concluded that any cut of meat containing any *E. coli* O157 is adulterated and unfit for human consumption. Pet. App. 14a. The state supreme court denied review without explanation. *Id.* at 44a.

SUMMARY OF ARGUMENT

I. This Court has jurisdiction, under 28 U.S.C.§ 1257, to review the Wisconsin Court of Appeals' decision that USDA is "powerless" (Pet. App. 19a) to interpret the meaning of "adulterated" under the FMIA. See *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 477 (1975). The decision below is the last word from a state court on an important federal issue that is potentially dispositive – indeed, *was* dispositive in the trial court – of the claims against petitioner. If review is denied, there may be no subsequent opportunity for this Court to address the court of appeals' decision because petitioner may prevail on non-federal grounds.

II. Review should be granted to protect the meat industry and consumers from the drastic consequences that would ensue if this nonsensical decision were permitted to stand. Apparently deeming itself better situated to interpret the non-self-defining term "adulterated" than the agency that has been regulating meat for 98 years, the Wisconsin Court of Appeals has disregarded the statutory and regulatory framework of the FMIA as well as years of experience and research by writing out of existence USDA's interpretation of "adulterated" – the single most important term in the FMIA – and replacing it with an unscientific and rigid interpretation of the statute. The court's reading destroys the national uniformity Congress intended to create and invites States to adopt interpretations of the FMIA that are in conflict.

To avoid potential liability, meat producers may have to comply – to the extent that they can – with divergent (and perhaps conflicting) standards from across the country, many of which – like the court of appeals' – would lack a valid scientific basis. The potential for harm – to meat processors and packers, including members of *amici*; to purchasers of meat products, including wholesalers, retailers, and restaurants that resell meat products; to consumers themselves; and to interstate commerce and the national economy – is difficult to overstate. The danger of the potential harms can be avoided only if the court of appeals' decision is reversed.

ARGUMENT

I. THIS COURT HAS JURISDICTION TO REVIEW THE WISCONSIN COURT OF APPEALS' DECISION

This Court's certiorari jurisdiction over decisions of the state courts is conferred by 28 U.S.C. § 1257, which authorizes review of any "[f]inal judgment[] or decree[] rendered by the highest court of a State in which a decision could be had."[7] The Court has long eschewed a "mechanical" interpretation of the requirement of "finality." *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 477 (1975). Instead, the Court has applied an "intensely practical approach" to determining "finality." *Mathews* v. *Eldridge*, 424 U.S. 319, 332 n.11 (1976); see also *Cox Broadcasting*, 420 U.S. at 478 & n.7 ("[T]he requirement of finality is to be given a practical rather than a technical construction.") (internal quotations omitted). See generally STERN & GRESSMAN at 145, 152-154.

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[7] The judgment of an intermediate state court is reviewable under 28 U.S.C. § 1257 when the highest state court declines to take the case. See ROBERT L. STERN, EUGENE GRESSMAN, STEPHEN M. SHAPIRO & KENNETH S. GELLER, SUPREME COURT PRACTICE 163, 165-167 (8th ed. 2002) (STERN & GRESSMAN).

In *Cox Broadcasting*, this Court noted four categories of cases in which it has treated decisions of the state courts as "final" even though "there [we]re further proceedings in the lower state courts to come." 420 U.S. at 477. As petitioner correctly points out (Pet. 16 n.4), this case falls squarely within the fourth category: cases in which (1) "the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court"; (2) "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come"; and (3) "a refusal immediately to review the state court decision might seriously erode federal policy." 420 U.S. at 482-483.

Each of those conditions is satisfied here. *First*, the Secretary's power to interpret the critical term "adulterated" under the FMIA was fully considered – and squarely resolved – below. And, if review is denied, it is possible that petitioner eventually will prevail on the merits on nonfederal grounds. See Pet. App. 4a ("We conclude that federal preemption does not close the doors of Wisconsin's courts to the claims against Excel; the merits of those claims still have to be determined.").

Second, if this Court were to reverse the decision below by holding that the Secretary's interpretation of "adulterated" is entitled to judicial respect, respondents' claims against petitioner could be finally resolved. That is precisely what the trial court decided, which led that court to enter judgment for petitioner on all claims against it. Pet. App. 52a-54a.

Third, the federal policy underlying the FMIA and its preemption clause would be seriously undermined if this Court declines to exercise immediate review. As its title suggests, the FMIA, including its express preemption clause, is aimed at ensuring nationwide uniformity in the standards for meat

produced for human consumption. See 21 U.S.C. § 602. The decision below destroys that uniformity by allowing state courts – and possibly state regulators as well – to impose additional or different requirements on meat producers.

In similar circumstances, this Court has repeatedly applied *Cox Broadcasting* to grant immediate review. See, *e.g.*, *Mississippi Power & Light Co.* v. *Mississippi*, 487 U.S. 354, 270 n.11 (1988) (explaining that the "critical federal question" was "ripe for review" even though a state court had decided the federal preemption question and remanded for further proceedings); *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174, 179-180 (1988) (granting review of a federal preemption question despite the pendency of additional state proceedings because leaving the state decision unreviewed would have threatened to undermine vital federal policies); *Southland Corp.* v. *Keating*, 465 U.S. 1, 6-7 (1984) (reviewing a state-court decision regarding federal preemption, even though claims had not yet been tried on the merits); *Belknap, Inc.* v. *Hale*, 463 U.S. 491, 497 n.5 (1983); *Local No. 438 Constr. & General Laborers Union* v. *Curry*, 371 U.S. 542, 548-551 (1963).

II. IF LEFT UNDISTURBED, THE COURT OF APPEALS' DECISION WOULD HAVE SERIOUS, HARMFUL, AND UNJUSTIFIED EFFECTS ON THE MEAT INDUSTRY AND CONSUMERS

The Wisconsin Court of Appeals failed to appreciate the magnitude and probable effects of its decision not only to strip the Secretary of her power to interpret key provisions of the FMIA but also to adopt a new judicial definition of "adulterated" without the benefit of the Secretary's experience, expertise, and guidance. The decision below does violence to the comprehensive, longstanding system of federal regulation in this area by eliminating the Secretary's power to interpret many provisions in the FMIA, leaving courts and state regulators to reach their own conclusions, and creating a regulatory leadership void in this important national industry. Failure to review it would result in the absence of the clarity, uniformity, and efficacy that

the statute plainly seeks and the current scheme provides. And the resulting uncertainty and inevitable confusion would adversely affect the price and availability of meat, and would lead to a fragmented, decentralized system under which the Nation's food supply will be *less* – not more – safe.

A. The Decision Below Would Destroy The Uniformity And Certainty That The Current System Was Designed To – And Does – Provide

Much of the statutory and regulatory structure of the FMIA turns on the interpretation of the term "adulterated." Under the FMIA, "adulterated" is the term used to describe meat that, for various reasons, must be condemned and destroyed. 21 U.S.C. §§ 604, 606. Meat that is deemed adulterated cannot be shipped or sold under the Act. *Id.* § 601. Processors who ship or sell adulterated meat face potential civil and criminal liability under federal law (*id.* §§ 671-676), and under state law (see *id.* § 678). See *Armour & Co.* v. *Ball*, 468 F.2d 76, 84 (6th Cir. 1972), cert. denied, 411 U.S. 981 (1973).

The meaning of "adulterated," however, cannot be gleaned from the statute alone. Indeed, the statutory definition of this crucial term encompasses meat that is "injurious to health," "filthy, putrid, or decomposed," or "insanitary," (21 U.S.C. § 601(m)(1), (3), (4)) – all terms whose meaning is far from clear from text alone unguided by science or experience. Despite the statute's lack of *textual* clarity, the meaning of "adulterated" was perfectly clear until the court of appeals issued its jarring decision: it was exactly as the Secretary prescribed based on experience and careful attention to the statute's various goals, including the protection of interstate commerce. Indeed, meat processing facilities across the country – as well as federal inspectors – have, until now, faithfully applied the Secretary's interpretation. Without the Secretary's guidance, meat processors could not possibly have predicted what would constitute "adulterated" meat.

Yet that is exactly the situation that meat processors will face if the decision below stands. If unable to rely on the Secretary's interpretation of "adulterated," meat processors are faced with great uncertainty – and enormous potential liability – regarding their production and sale of meat that USDA deems *un*adulterated. The court of appeals' decision opens the door to courts and regulators in other States to reach their own decisions regarding the meaning of "adulterated" and other key FMIA terms. It thus creates the distinct possibility that meat processors will be subject (after the fact) to as many as fifty sets of standards, some of which may conflict – as the standard adopted below does – with interpretations from the federal government and other States. Such a fragmented and decentralized scheme is perilous for a meat processor trying to ensure that its products comply with the laws.

Meat processors would not be the only group with this problem. Poultry and egg producers – who are subject to statutes with similar or identical language – may very well face the same dilemma. See Pet. 25-26 (citing the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-471); Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056. That is why *amici* representing the poultry industry join this brief.

Congress did not envision such a decentralized system, as the FMIA itself reveals. In the statute, Congress delegated to the Secretary the responsibility for prescribing certain rules and regulations (21 U.S.C. §§ 602, 608), for implementing and conducting on-site federal inspections (*id.* §§ 603, 604, 606, 621), and for taking action against violators of the statute and USDA regulations (*id.* §§ 671-676). Congress also prohibited States from imposing requirements that are "in addition to, or different" from, federal requirements imposed under the FMIA. See *id.* § 678; *National Broiler Council* v. *Voss*, 44 F.3d 740 (9th Cir. 1994) (holding that the PPIA and USDA's policy statements interpreting it preempted inconsistent state labeling laws); Letter from Richard E. Lyng, Sec'y of Agric., to George Deukmejian, Governor of Cal. (June 12, 1987) ("regulation by

the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated [in the FMIA and PPIA] are appropriate to prevent and eliminate burdens upon and effectively regulate [interstate and foreign] commerce as well as to protect the health and welfare of consumers (21 U.S.C. 451 and 602)"). These provisions indicate Congress's unmistakable intent to develop a detailed and uniform regulatory regime administered by the Secretary. Indeed, establishing uniform national requirements and preventing States from enforcing their own standards were the motivations for the 1967 amendments to the FMIA. See 60 Fed. Reg. 6774 ("The Wholesome Meat Act of 1967 * * * amended the basic laws governing mandatory meat * * * inspection to assure uniformity in the regulation of products shipped in interstate, intrastate, and foreign commerce."). The court of appeals' decision threatens to disassemble this regime.

The comprehensive federal regulatory regime that has developed serves its purpose well. Under the current scheme, approximately 7000 federal inspectors are stationed at thousands of federally inspected establishments. See Meat and Poultry Inspection: Report of the Sec'y of Agric. to the U.S. Cong. (Fiscal Year 2000) (FSIS Feb. 15, 2003), at 47, *available at* http://fsis.usda.gov/oa/congress/congress.htm. These inspectors monitor the slaughter and preparation of all meat and poultry products prepared for interstate commerce to ensure safety, wholesomeness, and accurate labeling and packaging. *Ibid.* In Fiscal Year 2000, FSIS inspected nearly 134 million head of livestock and more than 8.5 billion birds, and detained nearly 28 million pounds of adulterated meat and poultry products. *Id.* at 47, 35. The inspectors throughout the country conducted their inspections with a common understanding of the terms of the FMIA, including "adulterated." In the wake of the court of appeals' ruling, the certainty resulting from federal inspections would be abolished. Indeed, the definition of "adulterated" used by federal inspectors might bear little resemblance to the interpretation given to the term by officials in the State where

a cut of meat is eventually shipped or sold. Under that scenario, federal inspection is cold comfort to meat processors.

The court of appeals' decision also calls into question the Secretary's ability to set national priorities for the meat industry. Historically, the Secretary has been able to guide the meat industry by passing nationally implemented regulations and issuing informal guidance to facilities across the country. In response to those directives, meat processors have shifted resources towards the priorities set by the Secretary. See, *e.g.*, 67 Fed. Reg. 62,326 (interpretation designed to limit the prevalence of *E. coli* O157 in ground beef). The court of appeals' decision severely undercuts the Secretary's prospective ability to set national priorities for the meat industry. And, in light of the ever-present threat of terrorist actions against our national food supply[8] and the recent discovery of the first U.S. case of bovine spongiform encephalopathy (mad cow disease), the need for strong centralized authority could not be greater.[9]

By reading the FMIA in a way that eliminates USDA's power to interpret it, the court of appeals invites States to set their own food safety priorities. And those priorities, which would inevitably reflect local – not national – concerns, would lead to the demise of the national regulatory system.

B. The Decision Below Would Increase Cost and Confusion Without A Corresponding Improvement In Food Safety

If the meat industry adopts the court of appeals' interpretation of "adulterated" – as it may be forced to do if review

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[8] See FSIS Directive 5420.1 (March 17, 2003), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5420_1.pdf (explaining procedures in the event of a terrorist threat to the Nation's food supply).

[9] Federal initiatives designed to control the spread of mad cow disease – including the creation of a national cattle tracing system – can be accomplished only at the national level. See Margaret Webb Pressler, *Cattle-Tracing System Will Face Obstacles*, WASH. POST, Jan. 3, 2004, at E1.

is not granted – the effects on the meat industry and consumers will be significant. The court of appeals' decision would replace uniformity and predictability with uncertainty and confusion, leading to a decrease in the availability and affordability of meat products, hardship for the meat industry, and a less safe national meat supply. The court of appeals was wrong to believe that its interpretation of "adulterated" would serve the supposedly "overriding congressional purpose" of "public safety" (Pet. App. 10a).

To comply with the court's interpretation of "adulterated," all entities that sell meat – including slaughterhouses, meat processing plants, wholesalers, and retail establishments – would have to change complex production processes – even though such measures cannot guarantee that no *E. coli* O157 (or other natural pathogens) will exist on the meat when it reaches the ultimate consumer. Changes in the production process would raise production costs and lengthen production time. As a practical matter, the court of appeals' decision would mean that processing facilities would have to purchase the same number of animals, and run the same number of production lines, but would end up with fewer "unadulterated" cuts of raw meat (even though the "adulterated" meat poses little or no health risk). With higher costs and less product to sell, the industry – already known for its low profit margins[10] – would face even lower profitability, putting the entire industry in economic straits.

The increases in production costs that would be necessitated by the court's decision would inevitably be passed on to the consumer. *See* USDA, *Assessment of the Cattle and Hog Industries*, Calendar Year 2001 (2001 Assessment), 5, *available at* http://www.usda.gov/gipsa/pubs/01assessment/01assessment.pdf ("Retail prices reflect the total cost of producing, processing, distributing, and marketing meat and poultry products."). And all of this would occur at a time when the cost of beef is at

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[10] See Pressler, *supra* note 9, at E1.

an all-time high and the supply is at a seven-year low. See Blaine Harden, *Protein Diet Craze, Thin Supply of Cattle Fatten Ranchers' Wallets*, WASH. POST, Dec. 22, 2003, at A1. Cost increases could adversely affect consumers' ability to buy meat, leading to decreased consumption of it, especially in poorer segments of the population. See 2001 Assessment at 5 (changes in meat prices affects per capita consumption). And decreasing meat consumption can have negative nutritional and health consequences. See Fiona Bushell, *Food, Food, Food*, ENVTL. HEALTH J., Dec. 2001, *available at* http://www.ehj-online.com/archive/2000/december2001/december4.html.

C. The Decision Below Lacks A Valid Scientific Basis

What makes this parade of horribles all the worse is that there is no sound scientific basis for the Wisconsin Court of Appeals' approach. The court simply determined, without the benefit of expert, industry, or USDA assistance, that *E. coli* O157 on raw intact meat renders that meat "adulterated" because the bacteria *may* cause injury. Pet. App. 14a. The Secretary's interpretation, in contrast, is the product of cutting-edge scientific research and reasoned debate.

There is no valid scientific basis for the court's conclusion that raw intact cuts of meat with *E. coli* O157 present a significant health risk. The risk of illness from intact meat bearing *E. coli* O157 is "minuscule, regardless of the initial contamination level or susceptibility of the consumer," when the meat is adequately cooked. 67 Fed. Reg. 62,334; see also IFT Report at 27-28 (reporting a "low incidence of disease" associated with *E. coli* O157).[11] This scientific information formed the basis of the Secretary's decision to declare *E. coli* O157 an adulterant in ground – but not intact – beef products. See 64 Fed. Reg. 2804. Indeed, the Secretary explained that she

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[11] Indeed, the real problem – and the one that occurred in this case – is that preparers of raw meat often fail to take the recommended precautions to prevent cross-contamination. See Amanda Hesser, *Squeaky Clean? Not Even Close*, N.T. TIMES, Jan. 28, 2004, at D1.

"carefully considered the deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)" – an entity that makes scientific recommendations for the benefit of FSIS and the FDA[12] – before reaching the conclusion that "cuts of intact muscle (steaks) should be safe" if cooked properly because there is "a low probability of pathogenic bacteria being present in or migrating from the exterior surface to the interior of the beef muscle." *Id.* at 2803.

As it did when developing that standard, USDA continually monitors scientific developments and formulates reasoned approaches designed to control or, when possible, eliminate foodborne pathogens, which continue to evolve and mutate. The FSIS described its approach as follows:

> The Agency's continuing goal is to focus its efforts on addressing the true human health risks associated with meat, poultry, and egg products, as has been recommended by the National Academy of Sciences. We believe that this is best approached using a farm-to-table approach to microbial risk assessment to identify significant food safety hazards and identify potential strategies to prevent, reduce, or eliminate those hazards. * * * FSIS is working with other agencies and institutions to develop appropriate quantitative risk assessment methods and to support studies to fill data gaps needed to enhance the precision and reduce the uncertainty in risk characterizations.

Report to Cong. on the Consumer Safety Officer Initiative (FSIS Feb. 15, 2000), *available at* http://fsis.usda.gov/oa/congress/cso_report.htm. In addition to its relationship with NACMCF, FSIS obtains valuable information from the Centers for Disease Prevention and Control, the FDA's Center for Safety and Applied Nutrition, USDA's Agricultural Research Service, and the National Institute of Allergy and Infectious Disease. See 67 Fed. Reg. at 62,325-62,334; see generally CENTER FOR SAFETY & APPLIED NUTRITION, FOODBORNE

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[12] JOHNSON, *supra* note 3, § 6.2.

PATHOGENIC MICROORGANISMS AND NATURAL TOXINS HANDBOOK, *available at* http://cfscan.fda.gov/~mow/chap15.html; National Institute of Allergy and Infectious Disease, *Foodborne Diseases*, April 2002, *available at* http://www.niaid.nih.gov/factsheets/foodbornedis.htm.

Unlike the Secretary's considered judgment, the court of appeals' conclusion is based on nothing more than a simplistic analysis of ambiguous statutory text. In a world where the elimination of all foodborne pathogens is impossible,[13] USDA does the next best thing: it uses cutting-edge scientific information to develop standards for acceptable levels of harmful bacteria.

D. The Decision Below Is Blatantly Incorrect Because It Fails To Defer To The Secretary And To Consider The Statutory Objectives Collectively

Petitioner has adequately demonstrated the error of the decision below, but *amici* add a few words. The Wisconsin Court of Appeals was wrong in failing to defer to the Secretary's interpretation of "adulterated." The absence of formal rulemaking was certainly no excuse for failing to defer. See *Alaska Dep't of Envtl. Conservation* v. *EPA*, 2004 WL 86284, *16 (U.S. Jan. 21, 2004) ("Cogent administrative interpretations * * * not [the] product of formal rulemaking * * * nevertheless warrant respect."); *United States* v. *Mead Corp.*, 533 U.S. 218, 234 (2001) (deference should be given to agency guidance, "given the 'specialized experience and broader investigations and information' available to the agency * * * and given the value of uniformity in its administrative and judicial understandings of what a national law requires") (citations omitted); *Schuetz* v. *Banc One Mortgage Corp.*, 292 F.3d 1004, 1012-14 (9th Cir. 2002) (granting deference to an agency's policy statements that were published in the Federal Register but not the subject of formal rulemaking or adjudication), cert. denied, 537 U.S. 1171 (2003).

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[13] See generally IFT Report at 1-12; JOHNSON, *supra* note 3, § 3.6.

Technicalities of the *Chevron/Mead* doctrine aside – and the court below did not purport to rest its judgment on any such technicalities – the decision below reflects a woeful failure to recognize the sometimes-competing policy aims that ambiguous statutory language often reflects and that federal agencies may and must reconcile in light of experience. The court below reasoned that "*[t]he* focus of" the relevant subsections "is on people's health and safety." Pet. App. 19a (emphasis added). That singular focus blinded the court to the other statutory objectives – namely, promoting the national market for wholesome meat and protecting the meat industry from losses. See 21 U.S.C. § 602. "Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice – and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *PBGC* v. *LTV Corp.*, 496 U.S. 633, 646-647 (1990) (quoting *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987)). So too in the area of administrative interpretations of statutes, when "Congress intended to accommodate [multiple] interests, but did not do so itself on the level of specificity presented by" a case, it is not the business of non-expert judges to reach their own preferred reconciliation, let alone to pretend that one statutory goal trumps all others. *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 865 (1984).

The Wisconsin court did violence to an effective and proven statutory and administrative scheme, and did so on the basis of its own simplistic statutory analysis. This Court should not allow that result to stand.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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FEBRUARY 2004